REMARKS

Applicant wishes to thank the Examiner for the careful consideration given to the instant application. Currently, claims 1-6, 8-15 and 17-32 are pending. Claims 7 and 16 have been canceled and claims 8-10, 17, 18, 25, 29 and 30 have been amended. New claims 31 and 32 have been added. Applicant addresses each of the objects and rejections set forth in the Office Action below.

Specification

The Examiner has objected to the Abstract as not meeting the requirements under MPEP 608.01(b). Applicant has amended the Abstract to more fully correspond to the subject matter of the claims, thereby attending to the Examiner's objection.

The Examiner has requested that Applicant amend the specification to include an updated "Cross-References to Related Applications" Applicant has amended the first paragraph in accordance with the Examiner's request, thereby attending to the Examiner's objection.

Information Disclosure Statement

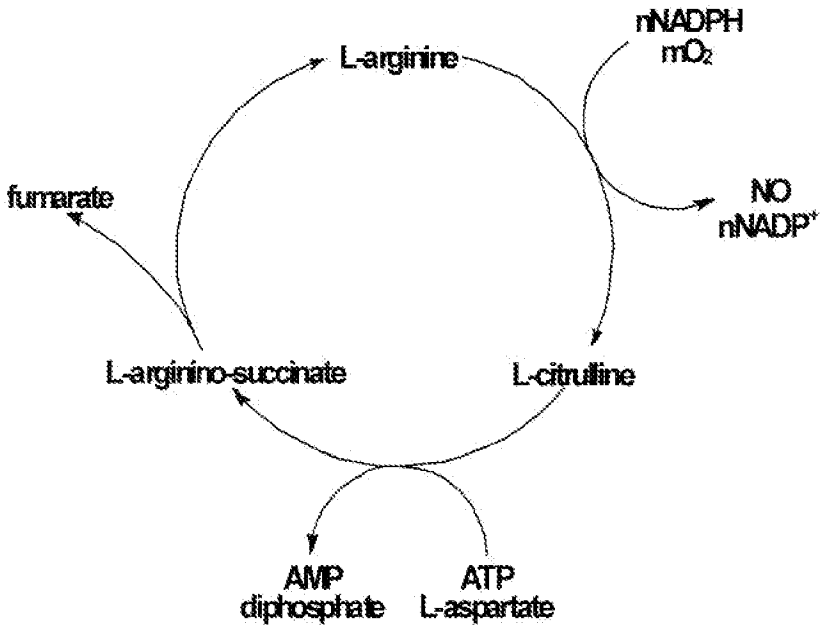
The Examiner has acknowledged receipt of two Information Disclosure Statements filed on October 1, 2004 and March 27, 2006, respectively, however has noted some incomplete bibliographic information. Applicant has submitted herewith a Supplemental Information Disclosure Statement together with the NPL references and requisite fee attending to these informalities.

35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-30 under 35 U.S.C. § 112, first paragraph as containing subject matter as not being adequately described. Applicant respectfully disagrees.

The specification contains more than adequate description that citrulline is an equivalent of arginine, and this is well understood in the art. In a brief telephone conference with the Examiner on June 7, 2008, it was pointed out that L-citrulline is a precursor to L-arginine as is specifically detailed in Applicant's patents and patent applications (e.g. U.S. Patent

No. 5,767,160). In other words, L-citrulline is a specific bioequivalent of L-arginine.. For example, in paragraphs [0014] and [0064], the specification states that L-arginine as used herein includes all biochemical equivalents.... Other bioequivalents of L-arginine may be arginase inhibitors, citrulline, ornithine, and hydralazine." In addition, the specification discloses that citrulline is a bioequivalent of L-arginine as shown in the L-arginine supply pathway (see paragraphs [0125] to [00127] and Figures 5 and 10). The L-arginine/L-citrulline pathway is represented in its below:



As taught by Applicant, citrulline is a degradation product of L-arginine and is recycled back into L-arginine, therefore one of ordinary skill in the art would understand that citrulline would have equivalent activity to L-arginine. L-citrulline has been used by Applicant in certain clinical trials. Accordingly, Applicant has provided adequate written description to convey that the Applicant had possession of the claimed invention and respectfully requests that this rejection be withdrawn.

Claim Objections

The Examiner has objected to claims 9 and 17 due to the recitation of "formulated in a form of administration." Application has amended claims 9 and 17 to recite that the composition is "formulated for a form of administration" in accordance with the Examiner's suggestion, thereby attending to the objection.

The Examiner has objected to claim 7 as containing a functional limitation, which is not given patentable weight in a composition claim. Applicant has canceled claim 7 and introduced new claims 31 and 32 to recite that the claimed methods include enhancing nitric oxide production, thereby attending to the Examiner's objection.

The Examiner has objected to claim 29 as improperly depending from itself. Applicant has amended claim 29 (and has also amended claim 30) to depend from claim 28, thereby attending to this objection.

35 U.S.C. § 112, second paragraph

The Examiner has rejection claims 10, 16 and 25 under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner states that claim 10 appears to be a pharmaceutical composition claim, but fails to specify a pharmaceutically acceptable carrier. Applicant has amended claim 10 to recite the composition further comprises a pharmaceutically acceptable carrier and has canceled claim 16, thereby attending to the Examiner's rejection.

The Examiner also indicates that claim 18 is incomplete because no specific disease condition to be treated has been specified. Claim 18 has been amended to further specify that the nitric oxide level in the subject being treated is increased, thereby indicating that subjects with disease conditions that require an increase level of nitric oxide should be treated with the composition. In light of the amendment and foregoing remarks, Applicant respectfully requests that this rejection be withdrawn.

The Examiner also states that in claim 25, the term "pharmaceutical carrier" is incomplete. Applicant has amended claim 25 to recite a "pharmaceutically acceptable carrier." Thereby attending to the Examiner's rejection. In addition, Applicant has amended claim 8 to recite the composition further comprises a pharmaceutically acceptable carrier, rather than a pharmaceutical carrier.

Non-statutory Double Patenting

The Examiner has rejected claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of co-pending U.S. Application No. 10/912,717. Applicant has filed herewith a terminal disclaimer with U.S. Application No. 10/912,717, thereby attending to this rejection.

The Examiner has provisionally rejected claims 18-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 23-26 and 28-34 of co-pending U.S. Application No. 10/207,399. Applicant has filed herewith a terminal disclaimer with U.S. Application No. 10/207,399, thereby attending to this rejection.

The Examiner has provisionally rejected claims 1-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-37 of co-pending U.S. Application No. 10/258,633. Applicant has filed herewith a terminal disclaimer with U.S. Application No. 10/258,633, thereby attending to this rejection.

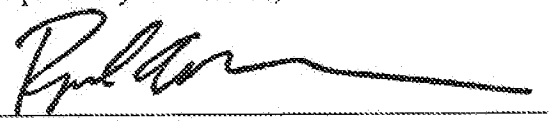
The Examiner has rejected claims 18-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,465,516. Applicant has filed herewith a terminal disclaimer with U.S. Patent No. 6,465,516, thereby attending to this rejection.

The Examiner has rejected claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,968,983. Applicant has filed herewith a terminal disclaimer with U.S. Patent No. 5,968,983, thereby attending to this rejection.

CONCLUSION

Applicant's attorney appreciates the recognition by the Examiner that there are no "references or combination of references anticipating or rendering obvious the instant claimed subjection matter". It is respectfully submitted that the Examiner's concerns regarding any informalities and the support for L-citrulline has been fully addressed, and that no further issues are outstanding. Accordingly, the present application should be immediately passed to issue and notice to such effect is respectfully requested. In the event that an additional fee is required for this amendment, the Commissioner is hereby authorized to charge such additional fee to Deposit Account no. 50-0436.

Respectfully Submitted,



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